

Serial No.: 10/549,567
Atty. Docket No.: P70821US0

REMARKS

The Office Action mailed July 10, 2008, has been carefully reviewed and Applicants note with appreciation the identification of allowable subject matter.

By this Amendment Applicants have amended claims 1, 2, 4, 7, 12 and 14-16. Claims 1-18 are pending in the application. Claims 1, 7, 12 and 14 are independent. Claim 18 has been withdrawn.

The Examiner objected to claims 1-17 as containing informalities which Applicants have corrected through the amendments set forth herein. Favorable reconsideration and withdrawal of the objection is therefore requested.

The Examiner rejected claims 1-4, 6-10 and 12-14 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,591,144 to Smith, and rejected claim 5 as being unpatentable over Smith in view of U.S. Patent No. 5,423,782 to Wolrich. The Examiner objected to claims 11 and 15-17 as being dependent on a rejected base claim, but stated that claims 11 and 15-17 would be allowable if rewritten in independent form to include the limitations of the underlying base claim.

While Applicants appreciate the identification of allowable subject matter, with the amendments set forth herein,

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claims 1, 7, 12 and 14 are also submitted as being in condition for allowance. Favorable reconsideration and allowance thereof is requested in view of the foregoing amendments and the following remarks.

As clarified in independent claims 1, 7, 12 and 14, the present invention is directed to an inner bag liner used with an ostomy appliance having a receiving bag. As provided in each of these claims, the receiving bag has a hole for receiving body wastes and a receiving bag bottom portion which defines the distal-most part of the receiving bag relative to the waste receiving hole. The inner bag liner has a waste entry hole for receiving body wastes and is folded along a plurality of folding lines so as to be compacted prior to use. The inner bag liner has a bottom portion *which defines the distal-most part of the inner bag liner relative to the waste entry hole both when the inner bag liner is folded and when the inner bag liner is fully unfolded* inside the receiving bag and reaches its distal-most position relative to the waste entry hole. When the inner bag liner is empty and folded along the folding lines, the inner bag liner bottom portion is in a folded position "adjacent" the waste entry hole, with "adjacent" being understood to be *relative to its unfolded position* since the inner bag liner bottom portion is always the distal-most part of

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the inner bag liner relative to the waste entry hole. As initial wastes exiting the stoma enter the bag, the wastes push against the inner bag liner bottom portion so that, as the folds unfold, the inner bag liner bottom portion moves away from its position adjacent the waste entry hole to its distal-most *position* relative to the waste entry hole as the inner bag liner is filled. This structural configuration in which the bottom portion of the inner bag liner has two positions, first being adjacent the waste entry hole of the inner bag liner when the bag is folded and empty and then, as the liner is filled by incoming waste, moving to its distal-most position relative to the waste entry hole when the inner bag liner is fully unfolded inside the receiving bag, is not shown or suggested by Smith.

Furthermore, the inner bag liner is releasably and reattachably attachable to the adhesive wafer worn by the user by means of a first coupling component. This releasable and reattachable feature allows the user to remove a used inner bag liner, attach a new inner bag liner and reuse the same receiving bag. This also is not shown by Smith.

Smith discloses a drainage bag including an outer bag 1 and an inner bag or liner 2. The liner 2 is fully extended within the outer bag at all times, with the two bags being manufactured as

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a unit in which the openings of both bags are thermo-welded to a flange 3. Hence, there is nothing in Smith to suggest that the inner bag could have a folded configuration in which the bottom portion of the inner bag is adjacent the waste entry hole when the bag is empty, and then be movable under the pressure applied by incoming waste against the bottom portion of the inner bag liner to cause the inner bag liner to unfold so that the inner bag liner bottom portion is moved to its distal-most position relative to the waste entry hole. Furthermore, in Smith the entire drainage bag is disposed of after a single use; there is no releasable and reattachable connection component in Smith that enables the outer bag of Smith to be reused while a used inner bag is replaced with a fresh inner bag.

As discussed in the remarks of the Amendment filed on April 29, 2008, according to the present invention, insertion of the new inner bag liner is facilitated by the folded condition in which the inner bag liner is configured prior to use. In addition to making it easier to exchange inner bag liners, the manner in which the inner bag liner is folded solves the problem of potential "pancaking" which can otherwise occur. Specifically, the initial entry of waste material into the inner bag liner can have a tendency to cause the sidewalls of the inner bag liner to adhere to

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one another, preventing the wastes from entering. This problem is avoided by the folded configuration of the inner bag liner which causes the entering wastes to *push against the bottom portion* of the inner bag liner, forcing it downward toward the bottom portion of the receiving bag as the liner is filled.

In Smith, on the other hand, since the outer bag is not reused by insertion of a new inner bag liner, there is no reason to have the inner bag liner in a folded configuration prior to use. On the contrary, the manufacturer of the Smith ostomy appliance would naturally provide the inner liner in the fully inserted and unfolded state, as shown in Smith, in order to avoid any problems, e.g., twisting, that could be associated with the unfolding of the inner bag. Hence, there is nothing in Smith to suggest any desirability for modifying the disclosed configuration of the inner bag, in which the inner bag is already in a fully extended orientation, to instead include a *folded* inner bag liner configuration that is unfolded only during use of the bag as claimed by the present invention.

For at least the foregoing reasons, claims 1, 7, 12 and 14 are patentable over the prior art. Favorable reconsideration and allowance thereof is requested. Claims 2-6, 8-11, 13 and 15-18 are also in condition for allowance as claims properly dependent on

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an allowable base claim, for the subject matter contained therein, and in view of the Examiner's identification of allowable subject matter (claims 11 and 15-17).

With this amendment and the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any questions or comments, or if a telephone interview could be effective in addressing any remaining concerns the Examiner may have, the undersigned would welcome the opportunity to discuss the claims with the Examiner so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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Date: December 8, 2008
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